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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/813,863

03/31/2004

Edward Vaquero

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5586

23702

7590

04/30/2008

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EXAMINER

LANG, AMY T

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

04/30/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/813,863	<b>Applicant(s)</b> VAQUERO, EDWARD	
	<b>Examiner</b> AMY T. LANG	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-13 and 22-28 is/are pending in the application.
- 4a) Of the above claim(s) 26-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-13, and 22-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of Invention 1, claims 1, 3-13, and 22-25 in the reply filed on 01/25/2008 is acknowledged.
2. Claims 26-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 01/25/2008.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

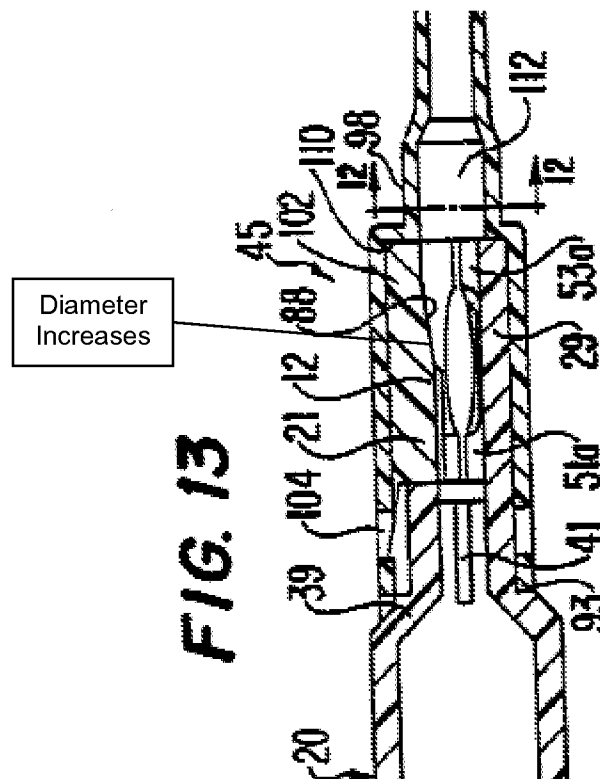
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 1, 3-6, 8, and 10** are rejected under 35 U.S.C. 102(b) as being anticipated by Figueroa (US 2002/0022881 A1).

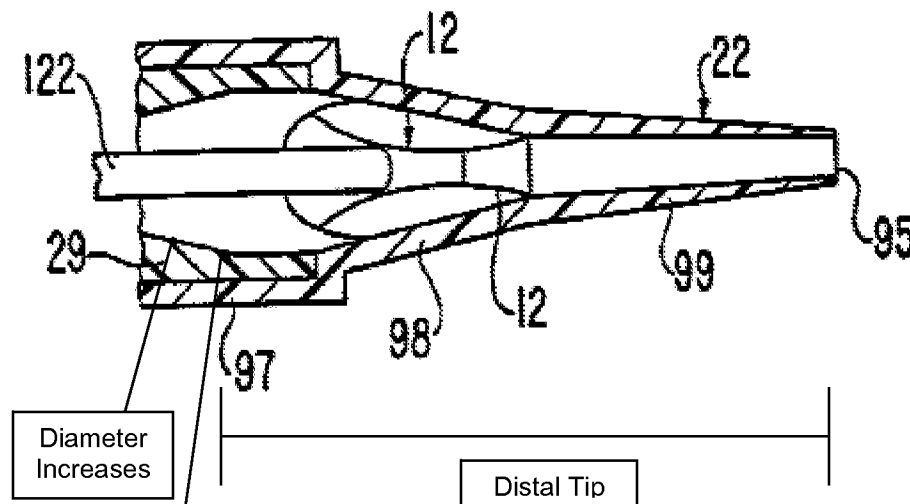
With regard to **claim 1**, Figueroa discloses a device for injecting a foldable IOL into an eye ([0006]). The device comprises body (16) and lumen (24), wherein the lumen terminates in a distal opening (95) (Figure 13). Shelf segment (29) defines an opening in the body between the proximal and distal ends of the device ([0044], [0045], [0046]).

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It is the examiner's position that the broadest reasonable interpretations of the claims teach wherein the lumen comprises a region that increases in diameter and that the lumen also terminates at an open tip. As shown in Figures 13 and 20 below, the lumen comprises a region that increases in diameter and terminates at open tip (95). Additionally, the "tip" of the lumen can also refer to the distal end of the lumen, not necessarily the very distal point. Therefore, the lumen comprises a region that increases in diameter and that terminates at the distal tip.



**FIG. 20**



With regard to **claim 3**, shelf segment (29) comprises leading edge (51a) and overlaps the instalar compressor drawer ([0044], Figure 14). The lens (12) is folded and compressed within the shelf segment (29) ([0049]).

With regard to **claims 4 and 5**, Figueroa further discloses the device as comprising a plunger (18) for pushing the IOL lens through the lumen ([0043]). As shown in Figure 1, the outer diameter of the plunger is slightly smaller than the inner diameter of the lumen.

With regard to **claim 6**, it is the examiner's position that the diameter of the lumen is substantially constant from the IOL holding point to the distal open tip (Figure 1).

With regard to **claims 8 and 10**, as shown in Figure 20, the increase of the diameter of the lumen is gradual.

5. **Claims 1, 3-8, 10, 12, and 22-25** are rejected under 35 U.S.C. 102(b) as being anticipated by Clark (US 6,491,697 B1).

With regard to **claims 1 and 7**, Clark discloses a device for injecting a foldable IOL into an eye comprising a body (22), an opening to receive an IOL (38), and a lumen (107) through cannula (28) (column 3, lines 62-64; column 6, lines 1-4). As shown in Figure 1, the lumen comprises a proximal end and an open tip (119). Clark further teaches wherein the cannula (28) comprises a proximal taper to compress the IOL (column 5, lines 58-63). As shown in Figures 1-3, the cannula flares outward from the proximal taper to form a region of increasing diameter. Therefore, the lumen (107), which runs the length of the cannula, also comprises a region of increasing diameter from the proximal taper.

With regard to **claims 3 and 22**, Clark further discloses a compressor drawer (40) comprising a leading edge (62) (column 4, lines 12-15). The compressor drawer moves from an open to a closed position to engage and compress the IOL (column 4, lines 28-40).

With regard to **claim 4**, the device also comprises a plunger (column 3, lines 50-54).

With regard to **claim 5**, lumen running through body (22) also overlaps the instantly claimed lumen. Since the plunger is inserted through this lumen, the plunger has a diameter slightly smaller than the diameter of the lumen.

With regard to **claim 6**, as shown in Figure 1, the device has an outer diameter that is substantially constant from the opening (38) to the open tip (119) since “substantially” is not narrowly defined.

With regard to **claims 8, 10, and 12**, as shown in Figures 1-3 of Clark, the region of increase is gradual.

With regard to **claims 23 and 24**, the proximal taper of the cannula (28) and lumen (107) forms a first diameter at a location that is proximate and distal to the distal end of the loading bay (38). The slightly flared distal end of the cannula and lumen forms a second diameter at a location that is intermediate the first location and the open tip (119). As shown in Figures 1-3, the second diameter is larger than the first diameter.

With regard to **claim 25**, it is the examiner’s position that the compressor of Clark overlaps the instantly claimed compressor drawer.

### ***Claim Rejections – 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. **Claims 7, 9, and 11-13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Figueroa (US 2002/0022881 A1).

Figueroa discloses a device for injecting a foldable IOL lens into an eye wherein the inner lumen increases in diameter. However, Figueroa does not teach wherein the outer diameter of the lumen increase along with the inner lumen or where the inner lumen increase is stepped.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the increase of the inner and outer diameter of the lumen because Applicant has not disclosed that either modification provides an advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the lumen disclosed by Figueroa because the lumen is able to receive an IOL lens. Therefore, it would have been an obvious matter of design choice to modify Figueroa to obtain the invention as specified in the claims.

9. **Claims 9, 11, and 13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark (US 6,491,697 B1).

Clark discloses a device for injecting a foldable IOL lens into an eye wherein the inner lumen increases in diameter. However, Clark does not teach wherein inner lumen increase in diameter is stepped.



At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the increase of the inner lumen to a stepped increase because Applicant has not disclosed the modification provides an advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a gradual increase, as disclosed by Clark, because the lumen is able to receive an IOL lens. Therefore, it would have been an obvious matter of design choice to modify Clark to obtain the invention as specified in the claims.

### ***Response to Arguments***

10. Applicant's arguments filed 10/09/2007 have been fully considered but they are not persuasive.

Specifically, applicant argues (A) that during the interview conducted 10/02/2007 the examiner indicated that if claim 1 were amended to recite a device having region of increasing diameter that terminates at the open tip, it would define over the prior art.

With respect to argument (A), no specific language was agreed upon during the interview to overcome the prior art of record.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY T. LANG whose telephone number is (571)272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

04/17/2008  
/Amy T Lang/  
Examiner, Art Unit 3731

/Todd E Manahan/  
Supervisory Patent Examiner, Art Unit 3731